

IN THE CLAIMS

Please amend the claims as follows:

Claim 1 (Previously Presented): A non-aqueous tape preparation comprising a nonaqueous adhesive mass consisting essentially of 1-30 parts by weight of a local anesthetic in a base form in 100 parts by weight of the nonaqueous adhesive mass base, 5-50% by weight of a styrene-isoprene-styrene block copolymer, 1-60% by weight of an alicyclic saturated hydrocarbon resin, 5-60% by weight of liquid paraffin and 1-30% by weight of butyl rubber,

wherein the adhesive mass is supported on a backing, and

wherein the local anesthetic is at least one selected from the group consisting of lidocaine, procaine, oxyprocaine, dibucaine, bupivacaine, mepivacaine, and propitocaine.

Claim 2 (Previously Presented): A tape preparation as claimed in Claim 1, wherein the effect of the local anesthetic lasts for 24 to 72 hours.

Claim 3 (Previously Presented): A tape preparation as claimed in Claim 1 which causes stratum corneum abrasion only to a slight extent even when applied continuously for a long period of time.

Claim 4 (Previously Presented): A tape preparation as claimed in Claim 1 which is excellent in duration of effect on alleviating pains due to herpes zoster or postherpetic neuralgia.

Claim 5 (Previously Presented): A tape preparation as claimed in Claim 1 which is excellent in duration of effect on alleviating pains on the occasion of high frequency therapy

or laser therapy, pains upon treatment of liver spots or dark red birthmarks, pains upon biopsy, pains on the occasion of skin grafting for the treatment of thermal burns, or pains on the occasion of treatment of molluscum contagiosum.

Claim 6 (Canceled).

Claim 7 (Previously Presented) A tape preparation as claimed in Claim 1, wherein the local anesthetic is lidocaine.

Claim 8 (Canceled).

Claim 9 (Canceled).

Claim 10 (Previously Presented): A tape preparation as claimed in Claim 1 which causes stratum corneum abrasion only to a slight extent even when applied continuously for a long period of time, and is excellent in duration of effect on alleviating pains due to herpes zoster or postherpetic neuralgia.

Claim 11 (Previously Presented): The preparation of Claim 1, wherein the alicyclic saturated hydrocarbon is present in an amount of from 10-50% by weight.

Claim 12 (Previously Presented): The preparation of Claim 1, wherein the styrene-isoprene-styrene block copolymer is present in an amount of from 10-40% by weight.

Claim 13 (Previously Presented): The preparation of Claim 1, wherein the liquid paraffin is present in an amount of 10-40% by weight.

Claim 14 (Previously Presented): The preparation of Claim 1, wherein the butyl rubber is present in an amount of from 5-15% by weight.

Claim 15 (Previously Presented): The preparation of Claim 1, wherein the butyl rubber has a molecular weight of not less than 400,000.

Claim 16 (Previously Presented): The preparation of Claim 1, wherein the local anesthetic in a base form is present in an amount of from 5-20% by weight.

Claim 17 (Previously Presented): The composition of Claim 1 further consisting essentially of a filler, an antioxidant or a mixture thereof.

Claim 18 (Previously Presented): The preparation of Claim 1, wherein the backing has a thickness of from 50-500  $\mu\text{m}$ .

Claim 19 (Previously Presented): The preparation of Claim 1, wherein the adhesive mass consists essentially of five parts of lidocaine, 22 parts of the styrene-isoprene-styrene block copolymer, five parts of the butyl rubber, 33 parts of the alicyclic saturated hydrocarbon resin, 30 parts of the liquid paraffin, 5 parts of titanium oxide, and 0.1 parts of an antioxidant.

REQUEST FOR RECONSIDERATION

Claims 1-5, 7 and 10-19 are active in the present application.

Applicants thank Examiner Gollamudi for the helpful and courteous discussion of August 5, 2004. During the discussion, Applicants' U.S. representative presented arguments that the Declaration under 37 C.F.R. § 1.132 submitted on January 29, 2004 was not given full consideration. Applicants' U.S. representation also pointed out that the compositions of at least one of the prior art references (Kubo) cited against the claims of the present application are cataplasms in contrast to the claimed invention which is a tape preparation. It was further pointed out that the "softener" of one of the prior art references (Kubo) is not disclosed to be a butyl rubber and that the applied prior art therefore does not teach changing the butyl rubber amount to affect the properties of adhesive compositions. The Examiner indicated that she may enter and consider a second Declaration under 37 C.F.R. § 1.132 comparing the claimed invention with the closest prior art.

The Office rejected the claims of the present application in view of JP10-147521 or JP07-126157 in combination with Kubo (U.S. 5,827,528) as obvious under 35 U.S.C. §103(a).

In the Office Action of April 16, 2004, the Office indicated that the Declaration under 37 C.F.R. §1.132 was insufficient for demonstrating the superiority of the claimed composition over the prior art compositions because the Declaration did not directly compare the claimed invention with the composition of the closest prior art, for example, JP10-147521.

Applicants submit herewith a Declaration under 37 C.F.R. §1.132 comparing a composition meeting the present claim limitations with a composition of JP10-147521 (Example 2 of the prior art). In Table A on page 2 of the Declaration the formulations for three compositions are described (a composition meeting the claim limitations (Invention

Preparation); a composition of JP10-147521 (D1 Preparation); and a Comparative Preparation). The composition of Example 2 of JP10-147521 does not contain butyl rubber whereas the Invention Composition disclosed in Table A contains 5 parts by weight of a butyl rubber.

The adhesive performance of the three compositions is compared in Table 1 of the Declaration. As is readily evident from Table 1 the Invention Preparation is able to provide significantly superior performance as evidenced by less “turn up” at 48 and 72 hours after application.

[Table 1]

	Number of persons (out of 20) showing the conditions of adhesion defined below								
	12 hours after application			48 hours after application			72 hours after application		
	No turn up	Slight turn up	Dropping	No turn up	Slight turn up	Dropping	No turn up	Slight turn up	Dropping
Invention preparation	20	0	0	20	0	0	18	2	0
D1 preparation	20	0	0	10	6	4	0	9	11
Comparative preparation	20	0	0	10	5	5	0	8	12

Further, as shown in Table 2 of the Declaration the Invention Preparation is able to provide substantially less stratum corneum abrasion (compare 0.13 for the invention composition vs. 0.200 for the JP10-147521 composition).

[Table 2]

Tested preparation	Amount of abraded stratum corneum (absorbance Abs/mL)
Invention preparation	0.130
D1 preparation	0.200
Comparative preparation	0.195

Applicants have therefore compared a composition meeting the present claim limitations with a composition disclosed in JP10-147521 (Example 2 of the prior art). Applicants have shown that a composition adhering to the present claim limitations provides significantly superior adhesive performance as evidenced by less “turn up” and “dropping” in

comparison to the prior art composition and further shows a lesser degree of stratum corneum abrasion.

Applicants submit that the claimed invention is not obvious in view of the prior art compositions in view of Applicants' showing of significantly superior performance for the claim composition with regards to its improved adhesiveness and lesser stratum corneum abrasion.<sup>1</sup>

The Office applied Kubo as support for the assertion that it is known to optimize the quantity of butyl rubber in adhesive compositions. For purposes of clarity Applicants note the following with regards to the disclosure of Kubo. The Kubo compositions are described with regards to the following elements:

- (A) a pressure sensitive adhesive component
  - (a) an elastomer
    - (a-1) a thermoplastic elastomer
    - (a-2) an elastomer having a low compatibility with the thermoplastic elastomer
  - (b) a softener
    - (b-1) a liquid rubber
  - (c) a tackifier
- (B) a water absorbing component.

The "butyl rubber" described in Kubo is mentioned only at column 4, lines 40-41. It is mentioned in the context of "(a-2) an elastomer having a low compatibility with the thermoplastic elastomer." The butyl rubber of Kubo is not identified as component (b) (e.g., the softener) which may contain (b-1) a liquid rubber or (c) a tackifier.

The softener and the tackifier of Kubo are described at column 4, line 51 to column 5, line 28, nowhere is butyl rubber disclosed as a softener.

The Office's statement in the Office Action of April 16, 2004 on page 6, first paragraph refers to the manipulation of an amount of a softener to affect the softness of a

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<sup>1</sup> Applicants note that, in a corresponding International Application, upon submission of the information provided in the Declaration attached herewith, all of the original claims were acknowledged to have novelty and non-obviousness. A copy of the International Preliminary Examination Report is attached herewith.

composition. As was mentioned above, the softener of Kubo is not relevant to the butyl rubber.

Therefore, the application of Kubo does not teach changing the butyl rubber concentration to affect the properties of the prior art adhesive mass. In the absence of such a teaching the combination of Kubo with JP10-147521 and JP07-126157 does not support a prima facie case of obviousness and the rejection should be withdrawn.

On page 7, first paragraph of the Office Action the Office states:

“in regards to the molecular weight of the butyl rubber, the examiner points out that column 4, lines 39-45 [of Kubo] wherein high molecular weight butyl rubber such as Kuraprene IR-10 (a MW of 850,000) are taught.”

Applicants note that Kuraprene IR-10 is not identified as a butyl rubber but instead as an isoprene rubber. Applicants wish to note for the record the following distinctions.

**Polyisoprene rubber:** a homopolymer of isoprene (a monomer having a carbon number of 5),

**Polybutene:** a polymer of butene (comprising polymerized isomers of butene such as isobutene and n-butene),

**Polyisobutylene:** a homopolymer of isobutylene,

**Butyl rubber:** a copolymer of isobutylene and isoprene.

In the Amendment and Request for Reconsideration filed on January 29, 2004, it was pointed out that the claimed invention is not obvious in view of the prior art relied upon by the Office at least because (i) the claimed composition contains an adhesive mass which is claimed in terms of “consisting essentially of” transitional language which excludes the water and the water-absorbing agents of one of the prior art references, and (ii) the Declaration under 37 C.F.R. § 1.132 submitted on January 29, 2004, demonstrates that the presence of water can materially affect the basic and novel characteristics of the claimed invention.

Kubo requires the presence of a water-absorbing agent. Such an element would be excluded in the presently claimed compositions by inclusion of the term “consisting essentially of”. Because Kubo requires the presence of water or a water-absorbing agent and

the claimed invention excludes the water and/or the water-absorbing agent of Kubo, and further because water may negatively affect the ability of a local anesthetic in base form to be delivered through the adhesive mass, Applicants submit that those of ordinary skill in the art would not turn to Kubo for guidance in reaching the claimed invention. Thus, there is no reasonable expectation of success in combining the disclosure of Kubo with the other cited prior art and the rejection should be withdrawn.

Moreover, Applicants submit that those of ordinary skill in the art would not have motivation to combine the disclosure of Kubo with either of JP10-147521 or JP07-126153 to arrive at the presently claimed invention because the Kubo prior art reference is drawn to a composition which absorbs liquids such as sweat and/or wound exudates whereas the claimed composition is “nonaqueous” and excludes the water and water-retaining agents of the prior art.

Further, Applicants submit that it is recognized by those of ordinary skill in the art that the anesthetic required to be present in the claimed compositions may exhibit poor solubility and/or compatibility with water. Therefore, one would not turn to the teachings of Kubo, which requires the presence of water or a water-retaining agent, to prepare the claimed tape preparation because water may negatively affect the ability of the composition to deliver the anesthetic in its base form.

Applicants therefore submit that the combination of prior art is not appropriate and thereby the rejection should be withdrawn.

The presently claimed invention is drawn to a “tape preparation” (e.g., a transdermal adhesive patch) having an adhesive mass supported on a backing. In contrast, in Kubo it is disclosed that the prior art medical adhesive compositions are:

“effective for use in the treatment of wounds, artificially made stomas, naturally formed fistulous openings, and other body openings for disposing of the incontinence of urine or feces, etc., and, in particular, in



applications where a large amount of exudates or body wastes are excreted from a patient.”

Kubo therefore describes a cataplasm that is much like a poultice (see entry for cataplasm at [www.dictionary.com](http://www.dictionary.com) which states: “See poultice.”; the entry for poultice at [www.dictionary.com](http://www.dictionary.com) states: “A soft moist mass of bread, meal, clay, or other adhesive substance, usually heated, spread on cloth, and applied to warm, moisten, or stimulate an aching or inflamed part of the body. Also called **cataplasm**.”)

A cataplasm or a poultice is normally packed into or onto a wound to heal the wound. In contrast, the claimed invention is drawn to a tape preparation. The claimed tape preparation is able to deliver the anesthetic over a long period of time in a reliable amount. In one embodiment, one can envision the claimed tape preparation as a way of administering a local anesthetic through the skin (e.g., a transdermal anesthetic patch). In contrast, a poultice may be inserted directly into a wound or onto an abrasion where there is no skin. The Kubo composition, while exhibiting some adhesive properties, must be able to absorb wound exudates and liquids.

The claimed non-aqueous tape preparation is therefore different from the Kubo cataplasm. The claimed nonaqueous tape preparation adheres to skin and delivers a local anesthetic in a reliable amount through the skin. The Kubo cataplasm on the other hand absorbs exudates and other liquids from a wound area. Applicants submit that the claimed non-aqueous tape preparation is different from the cataplasm of Kubo. Applicants submit that those of ordinary skill in the art may not turn to the Kubo composition, used for absorbing aqueous liquids such as wound exudates, as a guide for preparing adhesives which may deliver local anesthetics in their base form because the absorption of water into the adhesive is not compatible with reliable delivery of a local anesthetic in its base form.

Therefore, Applicants submit that the claimed non-aqueous tape preparation is not obvious in view of the prior art cataplasms and the rejection should be withdrawn.

In the Office Action of April 16, 2004, the Examiner indicated that a Declaration submitted with the Amendment of January 29, 2004 was insufficient for overcoming the rejections in view of Kubo and JP10-147521 and JP07-126157.

The Office has characterized the Declaration previously filed in this case as insufficient for demonstrating the patentability of the claimed invention. The Office stated that Applicants must submit evidence showing the criticality of the concentration of butyl rubber and the lack of obviousness in manipulating it (page 4 of the Office Action). The Office asserts on page 5 of the Office Action that the results of the previously submitted Declaration “demonstrate adhesiveness when the tape is immersed in water and not adhesiveness during typical wear.” In order to demonstrate that a composition has significantly superior or unexpectedly different properties in comparison to the prior art, it is not a requirement that the results reflect typical use. In fact, Applicants must show only that there is an unexpected result. So long as Applicants can demonstrate significantly superior or unexpectedly different properties, the evidence of the Declaration of January 29, 2004, is probative towards overcoming a *prima facie* case of obviousness.

The unexpected result may include the superiority of a property shared with the prior art (M.P.E.P. § 716.02(c)). Applicants have shown in the Declaration of January 29, 2004 that the claimed invention is superior (e.g. a composition that excludes water or a water absorbing agent has superior adhesiveness under watery conditions than compositions that contain water or a water-retaining agent).

The Office also characterized the Declaration of January 29 as “secondly, Applicant is demonstrating the degree of adhesiveness (which is not claimed) and not the adverse effect the component has on the composition.” Applicants note that it is not a requirement that the significantly superior performance or unexpectedly different properties used to evidence patentably be recited in the claims.

The Office further asserted that the Declaration of January 29 did not demonstrate the adverse effect of the prior art water-absorbing component in a composition (page 5, lines 4-6). Applicants submit however that Table 2 of the Declaration of January 29, 2004 shows that the number of adhesive patches separating from skin is substantially greater for compositions which contain a water-absorbing agent such as carboxymethylcellulose or gelatin in comparison to an invention composition.

Applicants submit that the Declaration under 37 C.F.R. § 1.132 submitted on January 29, 2004 was not given proper consideration in accordance with U.S. Patent and Trademark Office administrative procedure and pertinent case law on the matter (see MPEP § 716.01-716.02).

During the discussion of August 5, 2004 the Examiner indicate that she may enter and consider a new Declaration under 37 C.F.R. § 1.132 providing a side-by-side comparison of the closest prior art with the claimed invention.

Applicants respectfully request consideration of the Declaration under 37 C.F.R. § 1.132 submitted concurrently herewith (and discussed above).

Applicants therefore submit that those of ordinary skill in the art would not be motivated to combine the disclosure of Kubo with either or both of JP10-147521 or JP07-126157 because (i) none of the prior art references relied upon by the Office disclose that significantly different adhesive performance is achievable in the presence of a butyl rubber, (ii) at least one of the prior art references relied upon by the Examiner requires the presence of a component that may materially effect the performance characteristics of the claimed invention, and (ii) the cataplasm of each of the prior art references cannot render the claimed tape preparation obvious, Applicants further submit that the claimed invention is not obvious over the prior art as evidenced by the significantly superior performance of the claimed composition compared to the closest prior art.

Applicants request withdrawal of the rejections and passage of all new pending claims  
to Issue.

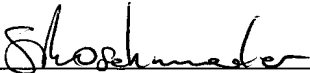
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Respectfully submitted,

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